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EXAMINER

NAQI, SHARICK

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/528,365	Applicant(s) TARASSENKO ET AL.	
	Examiner SHARICK NAQI	Art Unit 3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 29 December 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-11, 14, 15, 17-21, 23-25, 27, 36 and 37 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-11, 14-15, 17-21, 23-25, 27 and 36-37 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Objections

Claim 17 is objected to because of the following informalities: claim 17 is dependent on canceled claim 16.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11, 14-15, 17-21, 23-25, 27, and 37 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Independent claim 1, recites the following elements, "an electronic physiological data acquisition unit", "a data analyzer" and "an automatic message generator". It is unclear to the Examiner if the broadest reasonable interpretation of the claimed invention requires these elements to be interpreted as software, an algorithm, or some other non-tangible computer media, OR a computer, processor, or some form of computer tangible media. This is problematic because the broadest reasonable interpretation of the claim cannot be ascertained by the examiner. If "an electronic physiological data acquisition unit", "a data analyzer" and "an automatic message generator" are not directed to structural limitations than the terms have a different level of patentable weight then if the elements have a structural limitation such as a

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controller, processor or computer tangible media. It is the examiner's best guess in light of the broadest reasonable interpretation that "an electronic physiological data acquisition unit", "a data analyzer" and "an automatic message generator" are not structure, but are a form of software, an algorithm, or some other non-tangible computer media and as such the claim is indefinite.

The dependent claims and independent claim 37 are rejected based on the same reasoning presented in relation to claim 1 above.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6, 8-11, 14-15, 18-21, 23-25, 27 and 36-37 are rejected under 35

U.S.C. 103(a) as being unpatentable over Walker et al. US Patent Number 6,302,844 (hereinafter Walker) in view of Schulze.

In regards to claim 1, Walker discloses a telemedicine system comprising a patient-based physiological data acquisition and transmittal device connectable via a wireless network to transmit physiological data to a remote server, wherein the patient-based physiological data acquisition and transmittal device comprises:

an electronic physiological data acquisition unit which, under the control of a patient measures a physiological parameter of the patient to acquire and output data representing the parameter (*Walker fig 1, column 4, lines 49-68*);

a secure data store (*Walker column 4, line 51. memory*);

a wireless transmitter which upon receiving the output data from the data acquisition unit automatically transmits the output data via the wireless network to the remote server (*Walker column 3, lines 58-62, column 5, lines 1-7, column 7, lines 45-63. Data link*); and

wherein, if a connection to the wireless network is unavailable, the electronic physiological data acquisition unit performs the measurement, acquisition and output of data, and the patient-based physiological data acquisition and transmittal device stores the data in the secure data store and automatically transmits the stored data later when a connection to the wireless network is available (*Walker column 4, line 51, column 5, lines 45-57. Data is acquired and stored for a short time in order to be compressed and then transmitted*),

wherein the remote computer comprises a data analyzer and an automatic message generator to generate the messages (*Walker column 3, lines 58-67, column 4, lines 1-6, column 5, lines 45-57, column 6, lines 3-9, column 7, lines 45-63, column 20, lines 36-61 show that data is analyzed by the server and the alert/ pattern match settings updated based on patient's improving or degrading conditions (trend). Walker column 8, lines 18-39 shows that the server queries the patient based on alerts or pattern matches that are set based on patient's changing condition. Note column 5,*

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lines 45-57 discloses an embodiment where the analysis to determine the alert is done in the server instead of the patient device),

wherein the data analyzer automatically performs trend analysis of the data with reference to trends tuned to each patient's characteristics (*Walker column 3, lines 58-67, column 4, lines 1-6, column 5, lines 45-57, column 6, lines 3-9, column 7, lines 45-63, column 20, lines 36-61 show that data is analyzed by the server and the alert/pattern match settings updated based on patient's improving or degrading conditions. Walker column 8, lines 18-39 shows that the server queries the patient based on alerts or pattern matches that are set based on patient's changing condition. Note column 5, lines 45-57 discloses an embodiment where the analysis to determine the alert is done in the server instead of the patient device), and*

wherein the automatic message generator provides automatic responses to the patient-based physiological data acquisition and transmittal device based on the patient's condition as obtained from the data analyzer, the messages comprising questions to initiate interaction with the patient and being changeable by automatic download controlled by the server in response to changes in the patient's condition as measured by the electronic physiological acquisition unit (*Walker column 3, lines 58-67, column 4, lines 1-6, column 5, lines 45-57, column 6, lines 3-9, column 7, lines 45-63, column 20, lines 36-61 show that data is analyzed by the server and the alert/pattern match settings updated based on patient's improving or degrading conditions. Walker column 8, lines 18-39 shows that the server queries the patient based on alerts or pattern matches that are set based on patient's changing condition. Note column 5,*

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lines 45-57 discloses an embodiment where the analysis to determine the alert is done in the server instead of the patient device).

Walker further discloses in column 20, lines 42-45, that a signal is sent to the patient to appraise him/her of the situation when an alert is detected by the server and Walker also discloses in column 8, lines 34-39 that the server queries the patient in response to an alert. Walker does not state how the alert information signal or the query is presented to the patient. Walker does not disclose that the Patient Telemetry device has a display for displaying to the patient the data and messages related to the patient's condition or questions. However Schulze, a reference in an analogous art, discloses a monitoring system with a patient telemetry device that has a display for displaying alerts/alarm information and questions sent via a server for the user to answer (*Schulze figs. 4-6, paragraphs 00145-0146 and 0153*). It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Walker's patient telemetry device with Schulze's display to display received alert information and alert related questions, because the display presents the information in an easy and useable way for the patient (*Schulze paragraph 0146*).

Claim 2. A telemedicine system according to claim 1 wherein the wireless transmitter is adapted to receive automatically the output data from the physiological data acquisition unit on data acquisition thereby, and thereupon automatically to transmit the output data immediately in real time to the remote server if the connection

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to the wireless network is available (*Walker column 3, lines 58-62, column 7, lines 45-63*).

Claim 3. A telemedicine system according to claim 1 wherein the wireless transmitter is adapted to establish a connection to the wireless network automatically when it is switched on and to maintain the connection while switched on (*Walker column 3, lines 58-62, column 7, lines 45-63*).

Claim 4. A telemedicine system according to claim 1 wherein the wireless network is a packet-switched network (*Walker column 6, lines 12-15. Internet*).

Claim 5. A telemedicine system according to claim 4 wherein the wireless network is a public network (*Walker column 6, lines 12-15. Internet*).

Claim 6. A telemedicine system according to claim 5 wherein the wireless network is a General Packet Radio Service (GPRS) network (*Schulze paragraph 0176*).

Claim 8. A telemedicine system according to claim 1 wherein the wireless transmitter is one of a cellular telephone and a PDA (*Walker column 5, lines 1-7*).

Claim 9. A telemedicine system according to claim 8 wherein a software application is provided on the one of a cellular telephone and a PDA to interface with

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the physiological data acquisition unit and to control data transmission to the remote server (*Walker column 5, lines 1-7*).

Claim 10. A telemedicine system according to claim 1 wherein the patient-based data acquisition and transmittal device is adapted to check the acquired data for compliance with preset conditions (*Walker column 5, lines 57-66*).

Claim 11. A telemedicine system according to claim 10 wherein the preset conditions relate to the quality or completeness of the data or the condition of the patient (*Walker column 5, lines 57-66*).

Claim 14. A telemedicine system according to claim 1 wherein the remote server processes the data to check the condition of the patient and responds with said messages related to the patient's condition via the wireless network (*Walker column 20, lines 36-55*).

Claim 15. A telemedicine system according to claim 1 wherein the remote server formats the data for delivery and display to a clinician (*Walker column 20, lines 36-61*).

Claim 18. A telemedicine system according to claim 1 wherein the physiological data acquisition unit is one of: an electronic flow meter for recording Peak Expiratory

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Flowrate, an electronic blood glucose meter, a blood pressure monitor, and a heart rate monitor (*Walker column 4, lines 56-65*).

Claim 19. A telemedicine system according to claim 1 wherein the physiological data acquisition unit and wireless transmitter are integrated as a single device (*Walker fig. 1 Patient Telemetry Device 120-1*).

Claim 20. A telemedicine system according to claim 1 wherein the data sent from the wireless transmitter is time stamped with reference to a secure clock (*Walker column 4, lines 52-53. Clock circuit*).

Claim 21. A telemedicine system according to claim 20 wherein the secure clock is provided in the patient-based physiological data acquisition and transmittal device (*Walker column 4, lines 52-53. Clock circuit*).

Claim 23. A telemedicine system according to claim 1 wherein the data sent from the wireless transmitter is digitally signed (*Walker column 3, lines 57-58, column 4, lines 14-22*)

Claim 24. A telemedicine system according to claim 1 wherein the data sent from the wireless transmitter comprises the location of the wireless transmitter (*Walker column 6, lines 34-45*).

Claim 25. A telemedicine system according to claim 24 wherein information is sent from the server to the patient-based physiological data acquisition and transmittal device for display thereon and is adapted depending on the location of the wireless transmitter (*Walker column 6, lines 35-45, column 20, lines 36-55*).

Claim 27. A telemedicine system according to claim 1 wherein further information is sent from the server to the patient-based physiological data acquisition and transmittal device, and wherein in dependence upon the physiological parameter measurement and transmission to the server the further information comprises a prescription for medication (*Walker column 6, lines 16-34*).

Claims 36 and 37 are rejected using substantially the same reasoning applied in the rejection of claim 1 above.

Claim 7 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker and Schulze as applied to claim 1 above, and further in view of Haller et al. US Patent Publication No. 2002/0052539 (hereinafter Haller).

In regards to claim 7, Walker and Schulze teach in paragraph 0176 of Schulze that the CDMA wireless protocol is used in the device but other wireless networks will be just as suitable for use in the device. Schulze does not disclose that the wireless network is the 3G, PDC-P or EDGE network. However Haller, a reference in an

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analogous art, discloses, in paragraphs 0115-0141, the use of a 3G network in an emergency medical information communication system. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the wireless network of Walker and Schulze with Haller's 3G network because Haller teaches, in paragraphs 0115-0141, the interchangeability of different wireless networks, including CDMA and 3G.

Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over Walker in view of Schulze (hereinafter Walker modified) as applied to claim 1 above, and further in view of Baker, Jr. et al. US Patent No. 5,853,364 (hereinafter Baker).

In regards to claim 17, Walker modified discloses a data analyzer in the server (*Walker column 3, lines 58-67, column 4, lines 1-6, column 6, lines 3-9, column 7, lines 45-63, column 20, lines 36-61*). Walker modified does not disclose that the data analyzer comprises a Kalman smoother for smoothing the data. However Baker, a reference in an analogous art, discloses, in column 4, lines 4-25, the use of a Kalman filter to reduce noise energy in a system for measuring physiological parameters. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify Walker modified with the Kalman filter of Baker because Baker teaches in column 4, lines 4-25 and column 9, lines 58-60, that the Kalman filter optimally filters noise from physiological measurements and further teaches, in column 11, lines 22-36, that the Kalman filter improves accuracy of the results.

Response to Arguments

Examiner has further clarified the rejection and applicant's arguments with respect to claims 1-11, 14-15, 17-21, 23-25, 27, and 36-37 have been considered but are moot in view of the new ground(s) of rejection.

This action is made non-final because of the new rejections presented under 35 U.S.C. 112, second paragraph, for the terms "an electronic physiological data acquisition unit", "a data analyzer" and "an automatic message generator".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to SHARICK NAQI whose telephone number is (571)272-3041. The examiner can normally be reached on 8:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry M. Johnson III can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/S. N./

Examiner, Art Unit 3769

/Michael C. Astorino/

Primary Examiner, Art Unit 3769

March 27, 2009